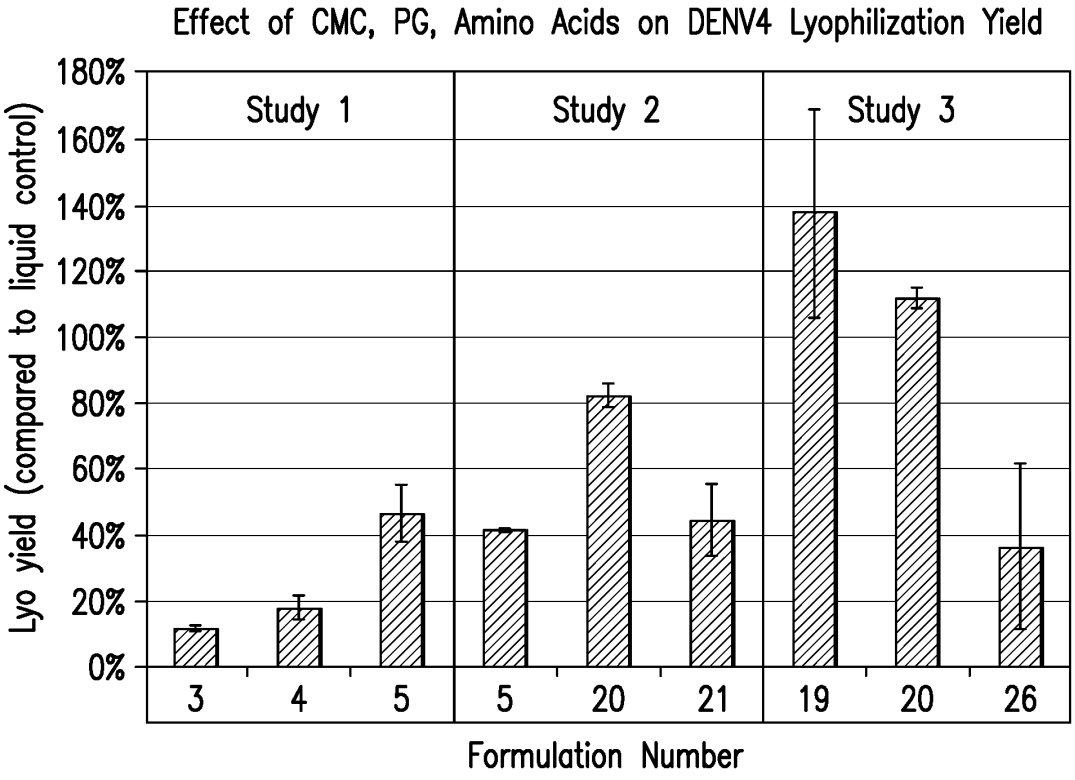

Effect of CMC, PG, Amino Acids on DENV4 Lyophilization Yield
Lyo yield (compared to liquid control)
180%
160%
140%
120%
100%
80%
60%
40%
20%
0%
Study 1
Study 2
Study 3
3
4
5
5
20
21
19
20
26
Formulation Number

FIG. 1

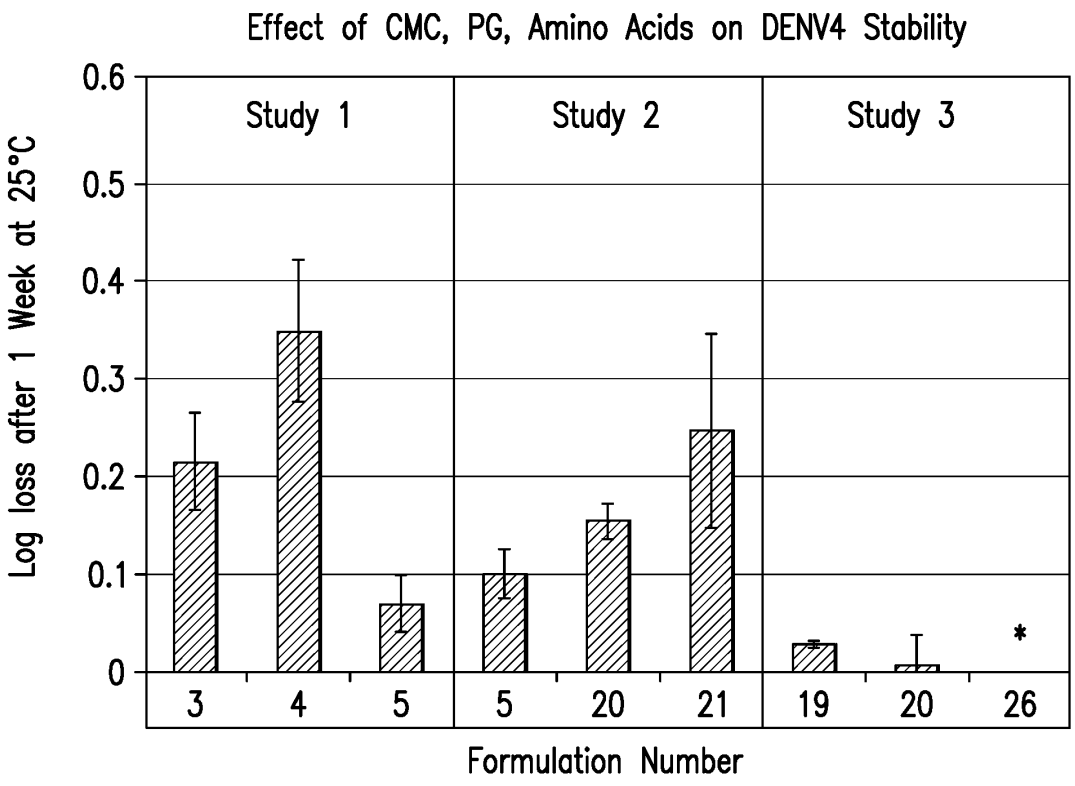

Effect of CMC, PG, Amino Acids on DENV4 Stability
Log loss after 1 Week at 25°C
0.6
0.5
0.4
0.3
0.2
0.1
0
Study 1
Study 2
Study 3
3
4
5
5
20
21
19
20
26
*
Formulation Number

FIG.2

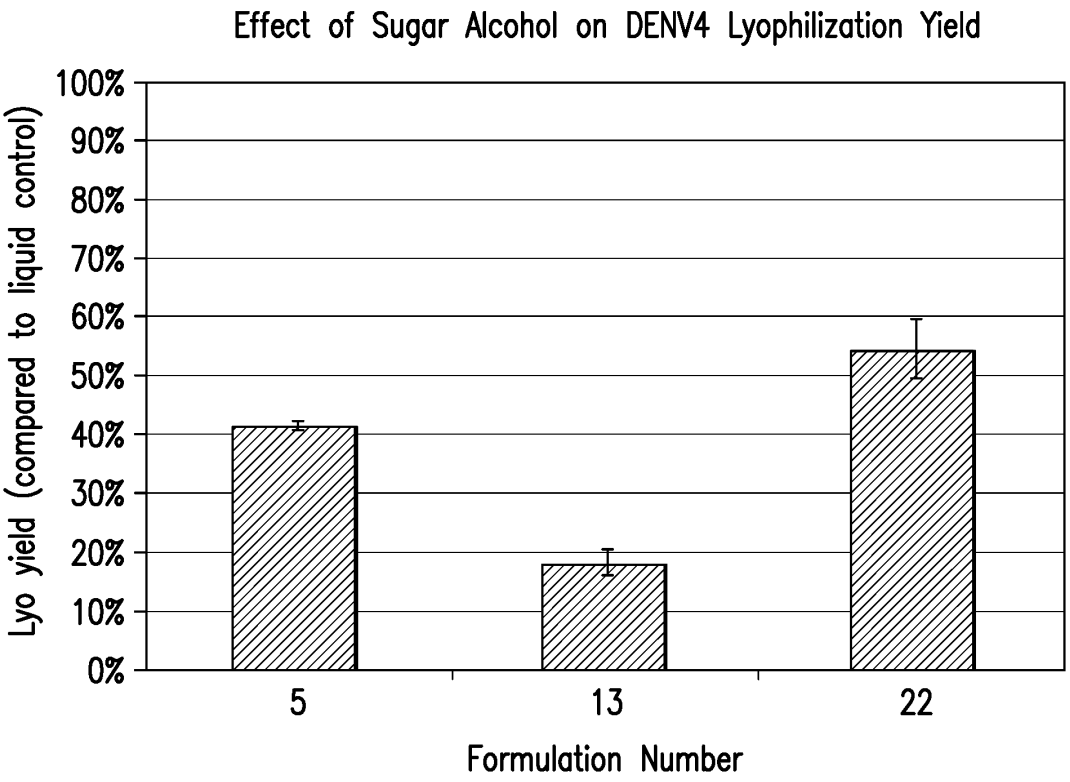

Effect of Sugar Alcohol on DENV4 Lyophilization Yield
Lyo yield (compared to liquid control)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
5
13
22
Formulation Number

FIG.3

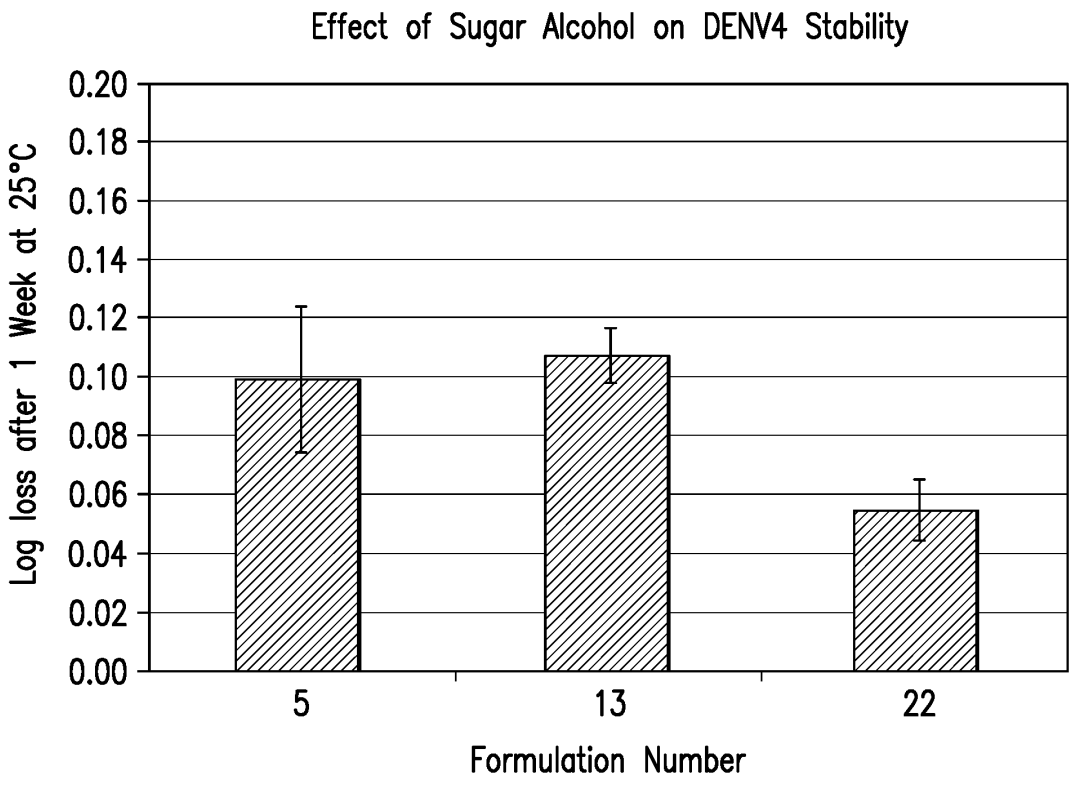

Effect of Sugar Alcohol on DENV4 Stability
Log loss after 1 Week at 25°C
0.20
0.18
0.16
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00
5
13
22
Formulation Number

FIG.4

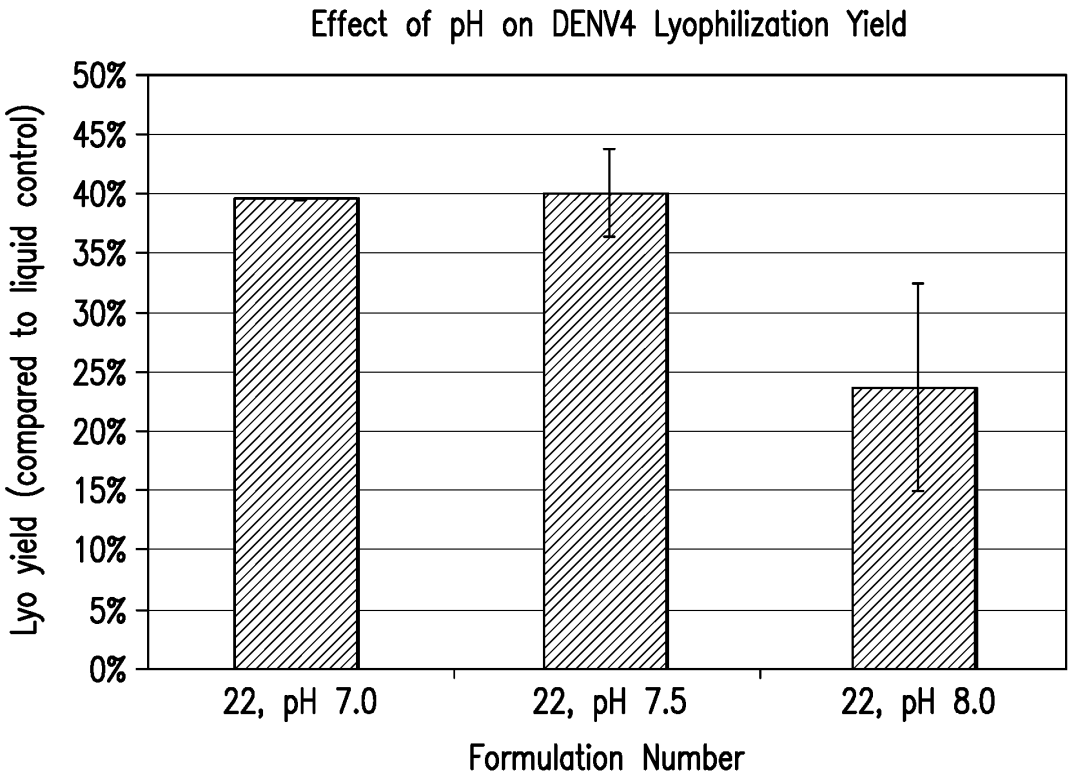

Effect of pH on DENV4 Lyophilization Yield
Lyo yield (compared to liquid control)
50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
22, pH 7.0
22, pH 7.5
22, pH 8.0
Formulation Number

FIG.5

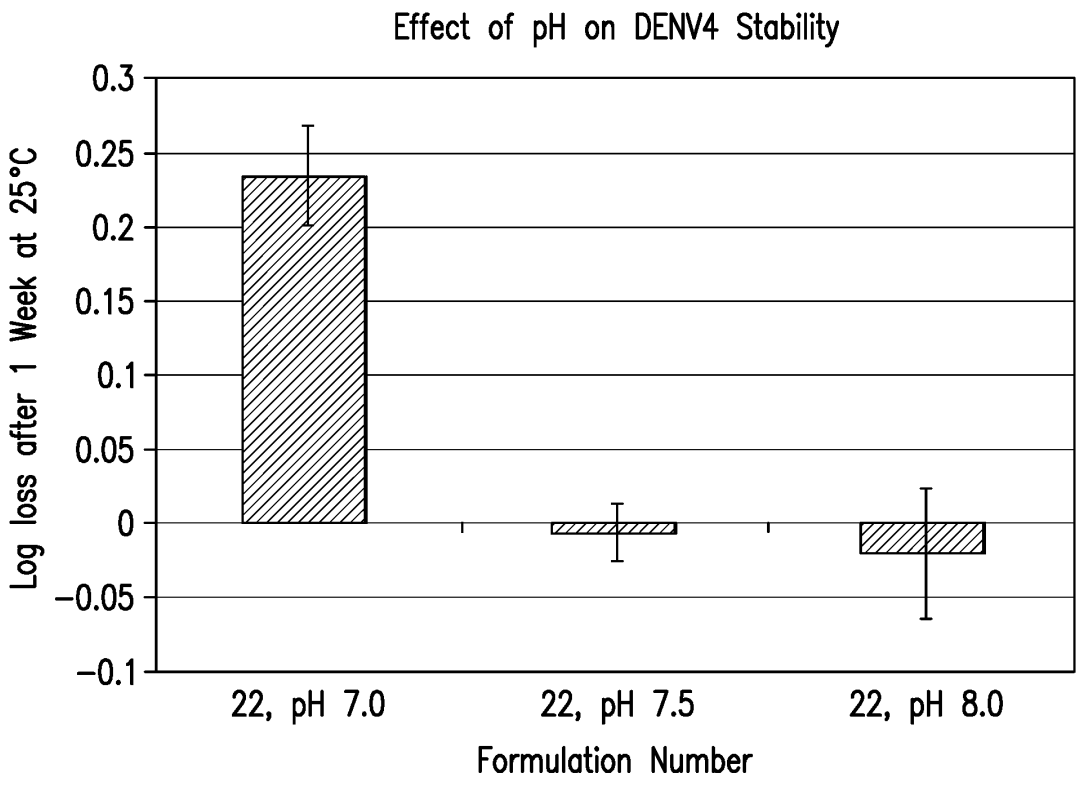

Effect of pH on DENV4 Stability
Log loss after 1 Week at 25°C
0.3
0.25
0.2
0.15
0.1
0.05
0
−0.05
−0.1
22, pH 7.0
22, pH 7.5
22, pH 8.0
Formulation Number

FIG.6

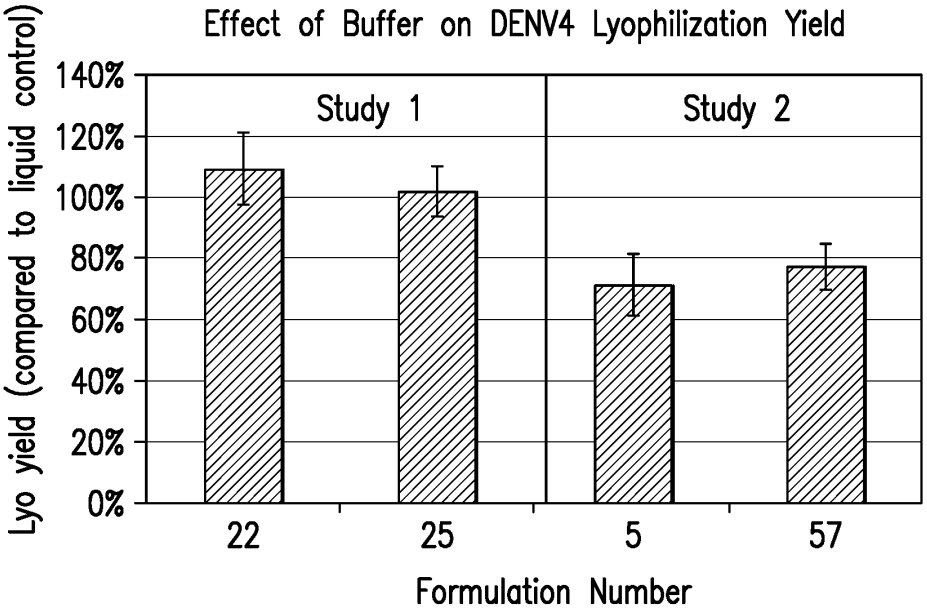

Effect of Buffer on DENV4 Lyophilization Yield
Lyo yield (compared to liquid control)
140%
120%
100%
80%
60%
40%
20%
0%
Study 1
Study 2
22
25
5
57
Formulation Number

FIG.7

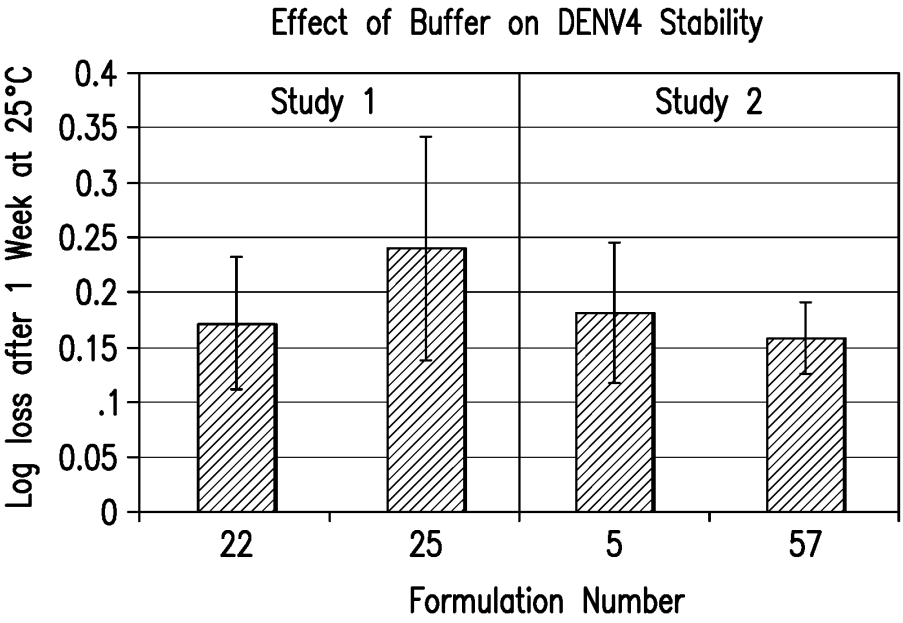

Effect of Buffer on DENV4 Stability
Log loss after 1 Week at 25°C
0.4
0.35
0.3
0.25
0.2
0.15
.1
0.05
0
Study 1
Study 2
22
25
5
57
Formulation Number

FIG.8

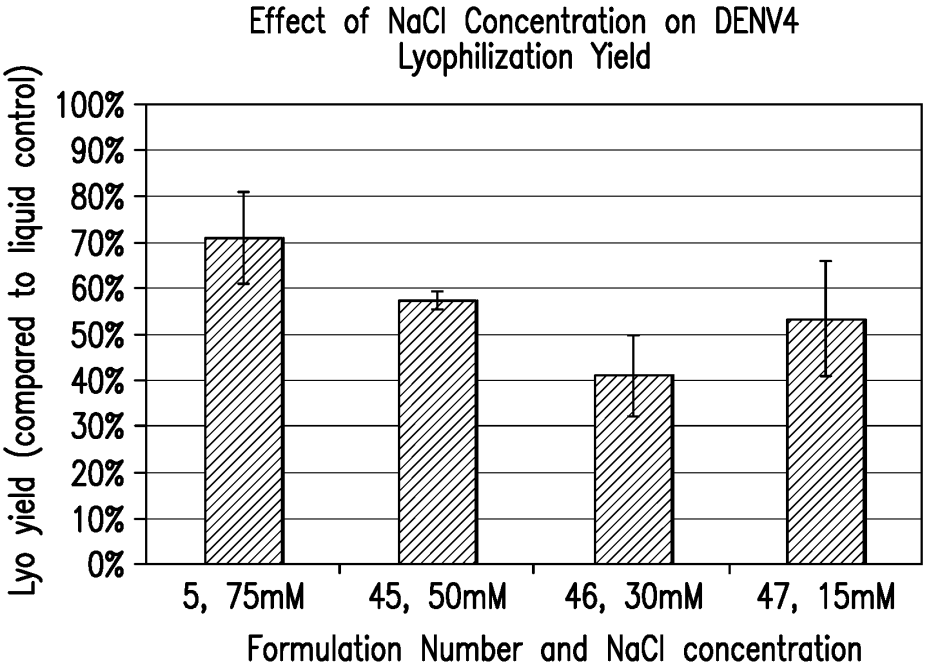

Effect of NaCl Concentration on DENV4 Lyophilization Yield
Lyo yield (compared to liquid control)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
5, 75mM
45, 50mM
46, 30mM
47, 15mM
Formulation Number and NaCl concentration

FIG.9

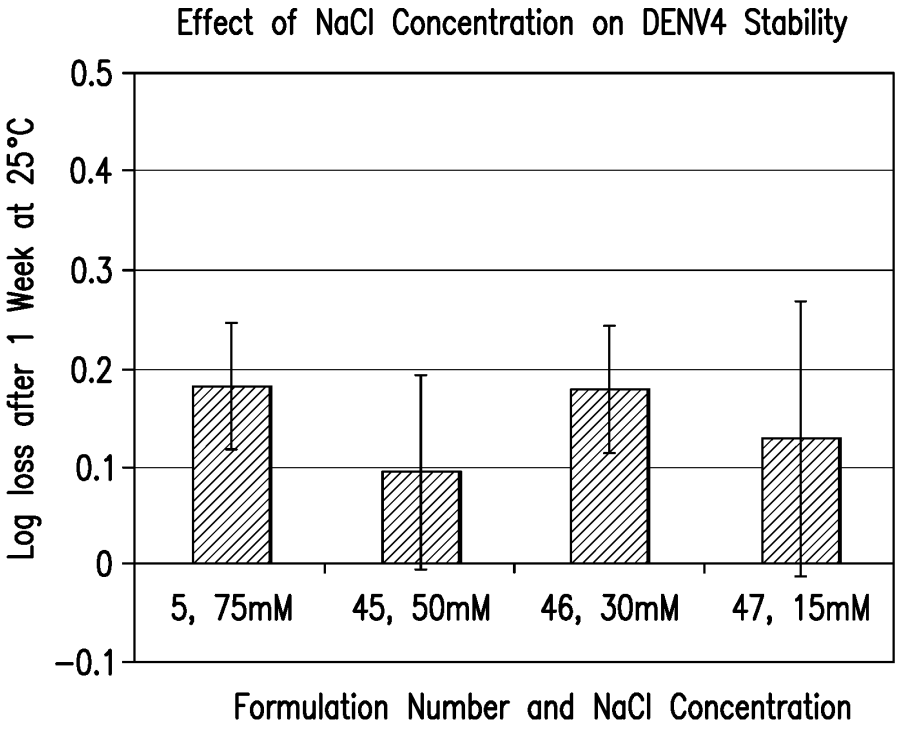

Effect of NaCl Concentration on DENV4 Stability
Log loss after 1 Week at 25°C
0.5
0.4
0.3
0.2
0.1
0
−0.1
5, 75mM
45, 50mM
46, 30mM
47, 15mM
Formulation Number and NaCl Concentration

FIG.10

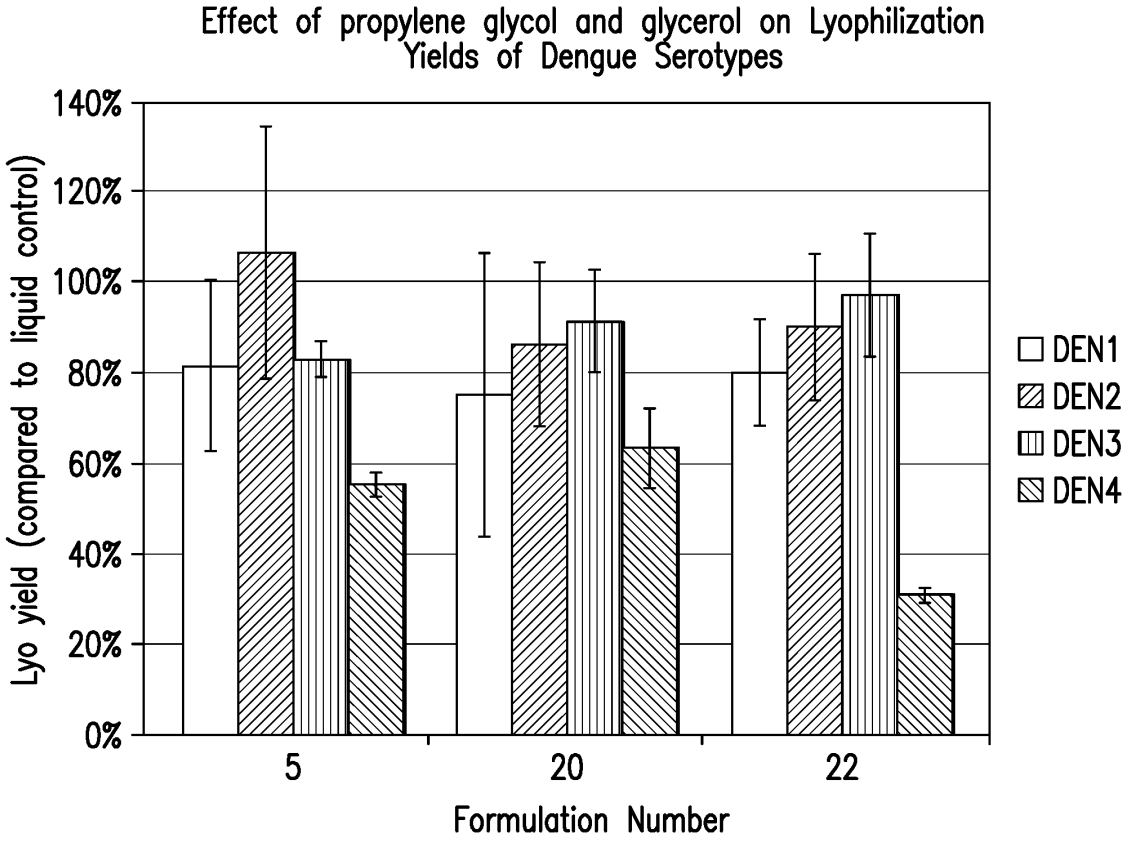

Effect of propylene glycol and glycerol on Lyophilization Yields of Dengue Serotypes
Lyo yield (compared to liquid control)
140%
120%
100%
80%
60%
40%
20%
0%
5
20
22
Formulation Number
DEN1
DEN2
DEN3
DEN4

FIG.11

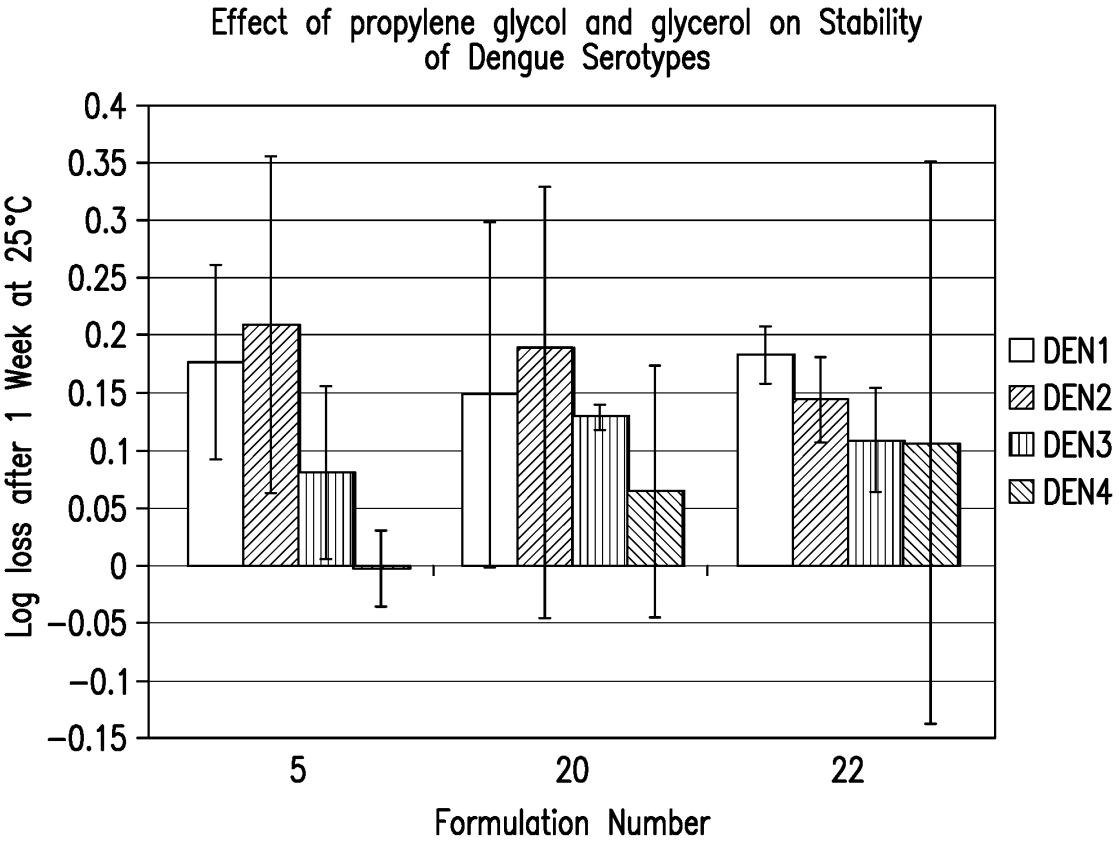

Effect of propylene glycol and glycerol on Stability of Dengue Serotypes
Log loss after 1 Week at 25°C
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
−0.05
−0.1
−0.15
5
20
22
Formulation Number
DEN1
DEN2
DEN3
DEN4

FIG.12

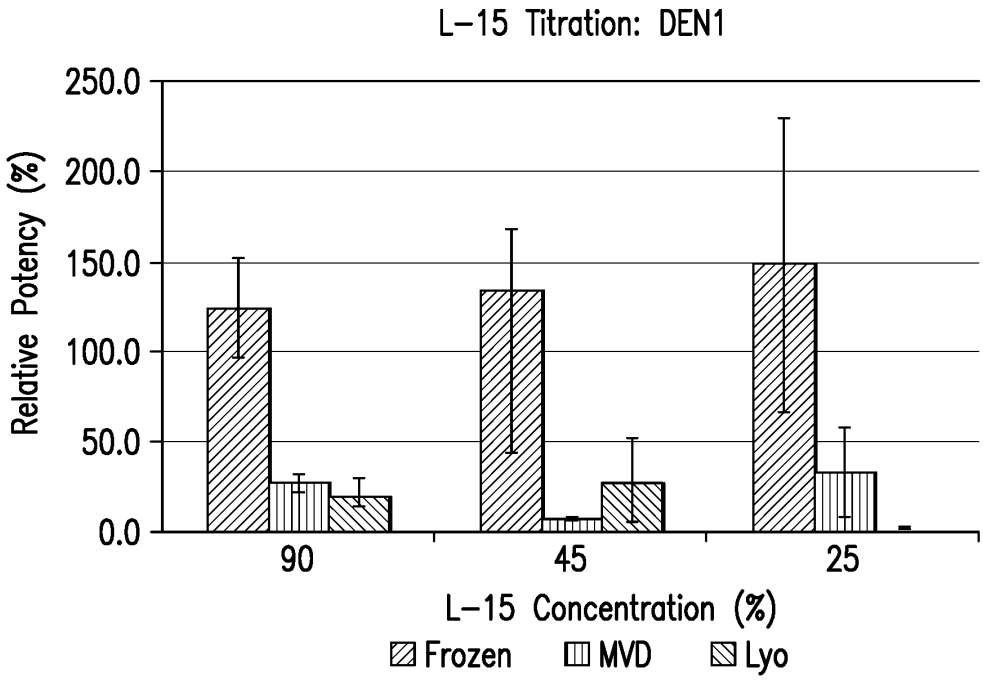

L-15 Titration: DEN1
Relative Potency (%)
250.0
200.0
150.0
100.0
50.0
0.0
90
45
25
L-15 Concentration (%)
Frozen
MVD
Lyo

FIG.13

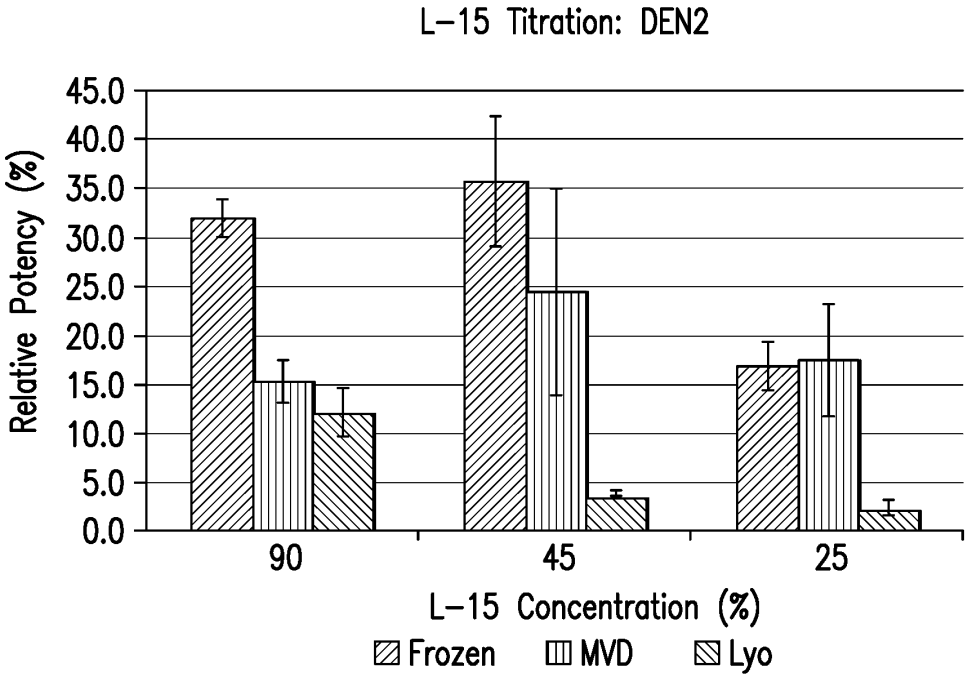

L-15 Titration: DEN2
Relative Potency (%)
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
90
45
25
L-15 Concentration (%)
Frozen
MVD
Lyo

FIG.14

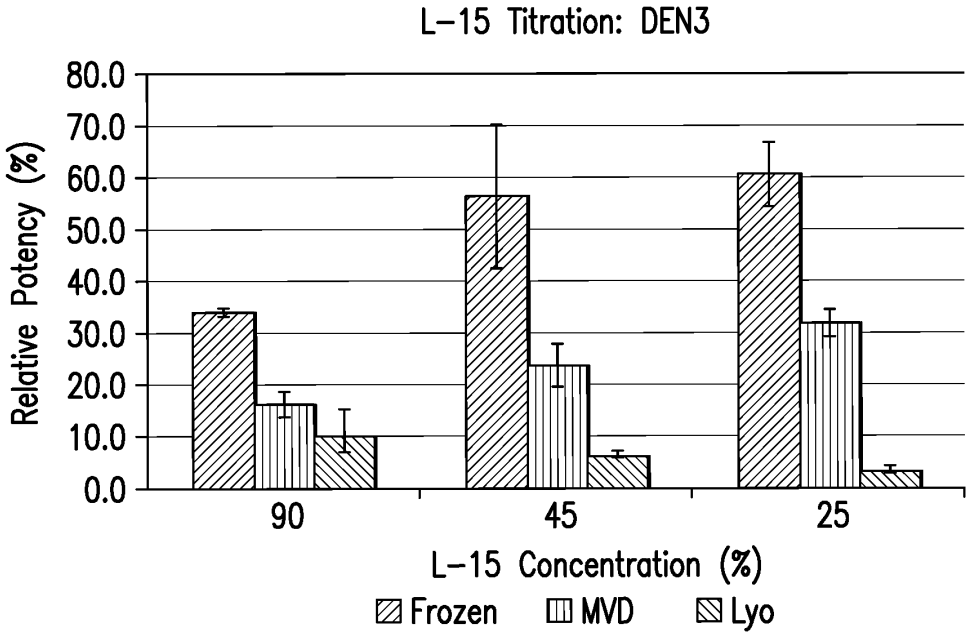

L-15 Titration: DEN3
Relative Potency (%)
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
90
45
25
L-15 Concentration (%)
Frozen
MVD
Lyo

FIG.15

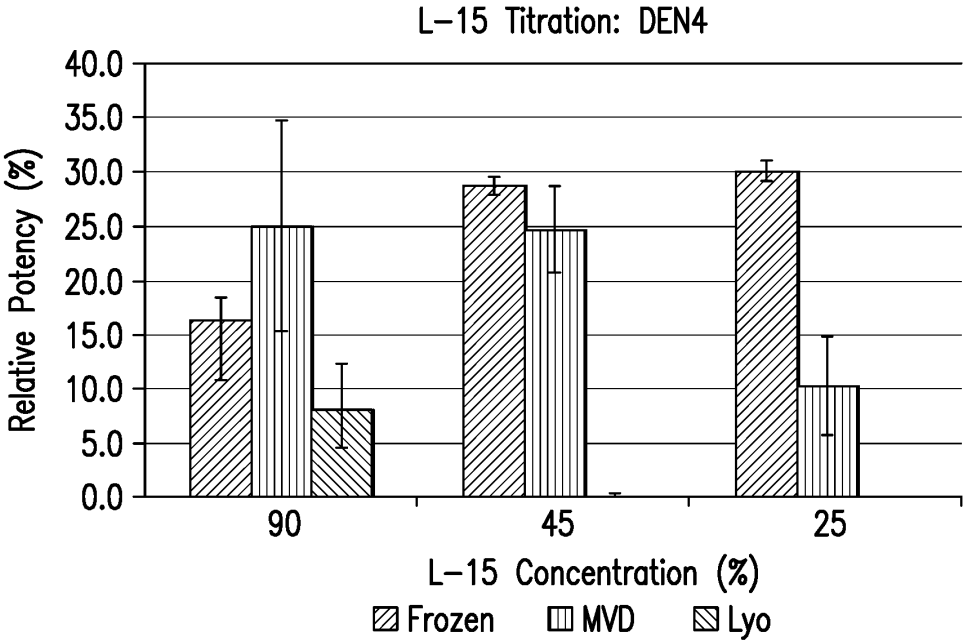

L-15 Titration: DEN4
Relative Potency (%)
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
90
45
25
L-15 Concentration (%)
Frozen
MVD
Lyo

FIG.16

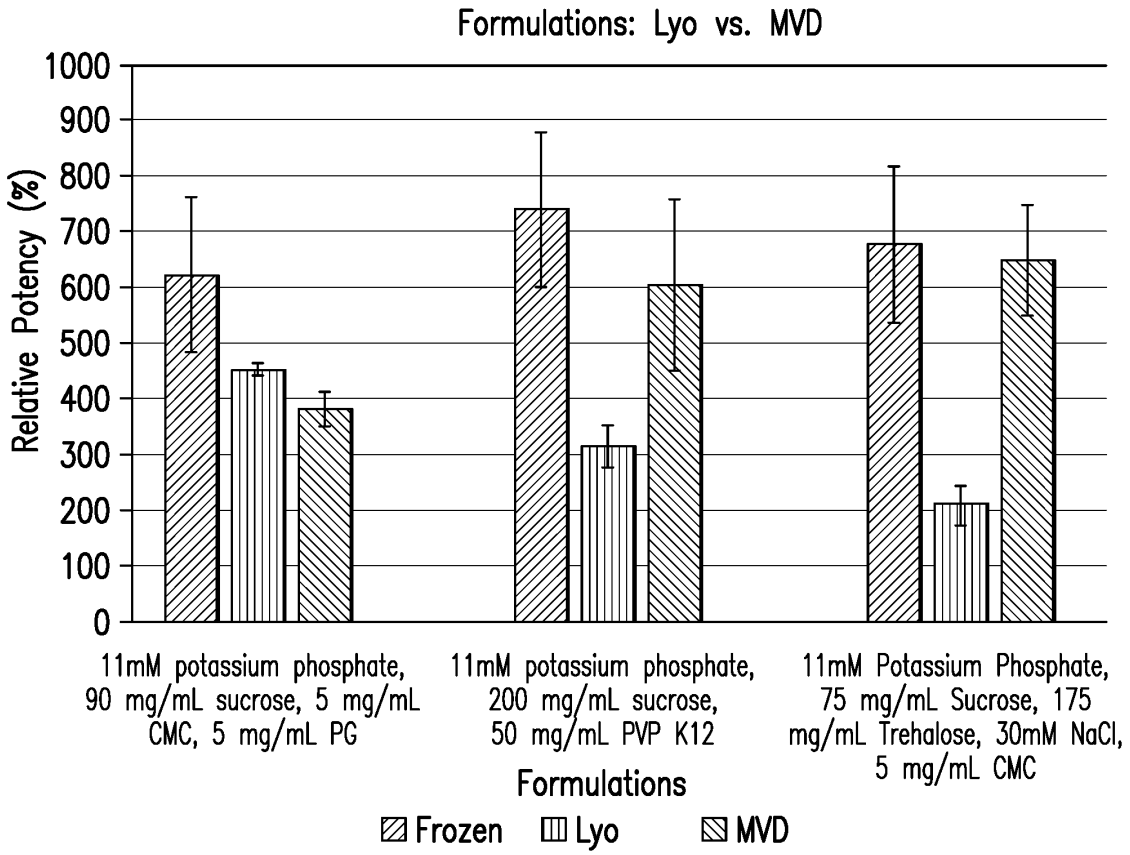

Formulations: Lyo vs. MVD
Relative Potency (%)
1000
900
800
700
600
500
400
300
200
100
0
11mM potassium phosphate, 90 mg/mL sucrose, 5 mg/mL CMC, 5 mg/mL PG
11mM potassium phosphate, 200 mg/mL sucrose, 50 mg/mL PVP K12
11mM Potassium Phosphate, 75 mg/mL Sucrose, 175 mg/mL Trehalose, 30mM NaCl, 5 mg/mL CMC
Formulations
Frozen
Lyo
MVD

FIG.17

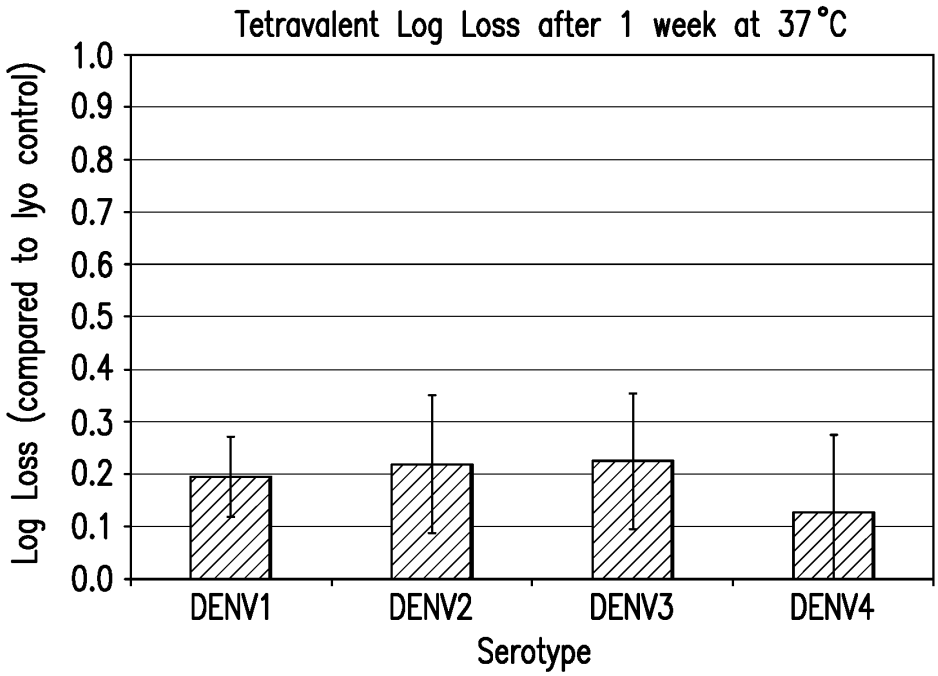


FIG.18A

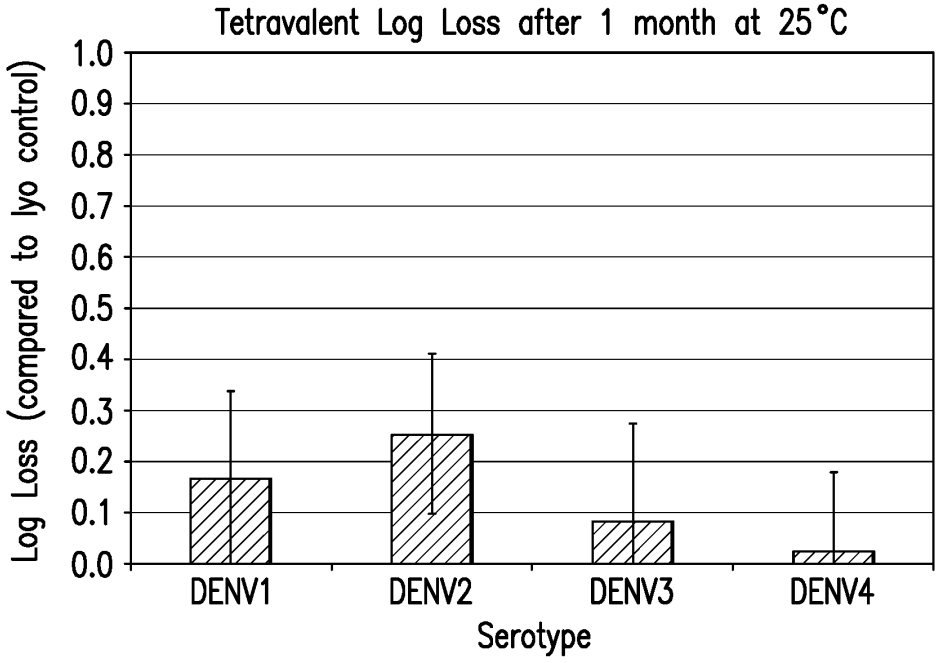


FIG.18B

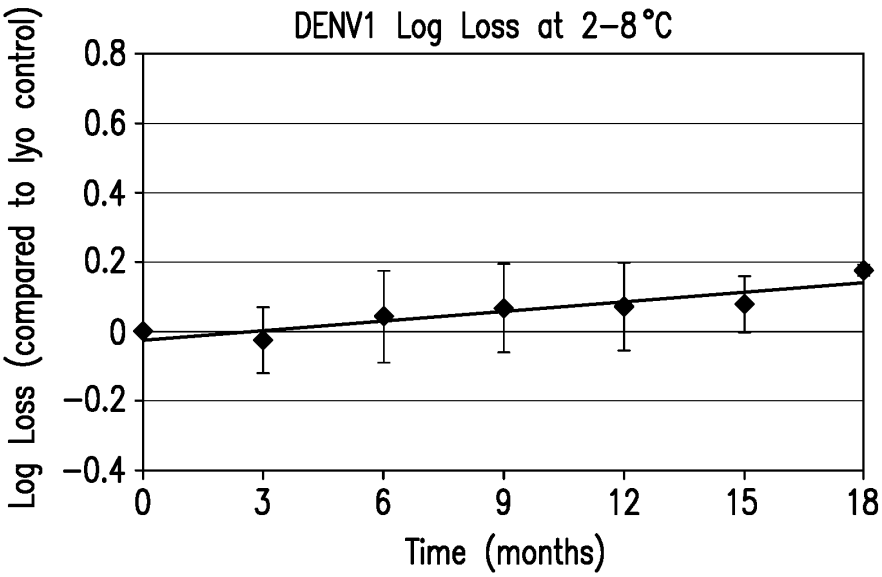


FIG.19A

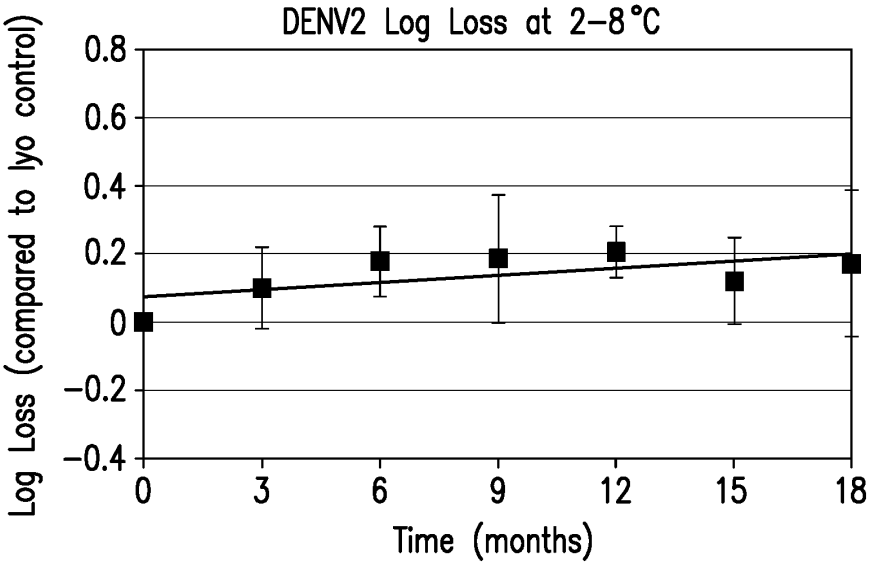


FIG.19B

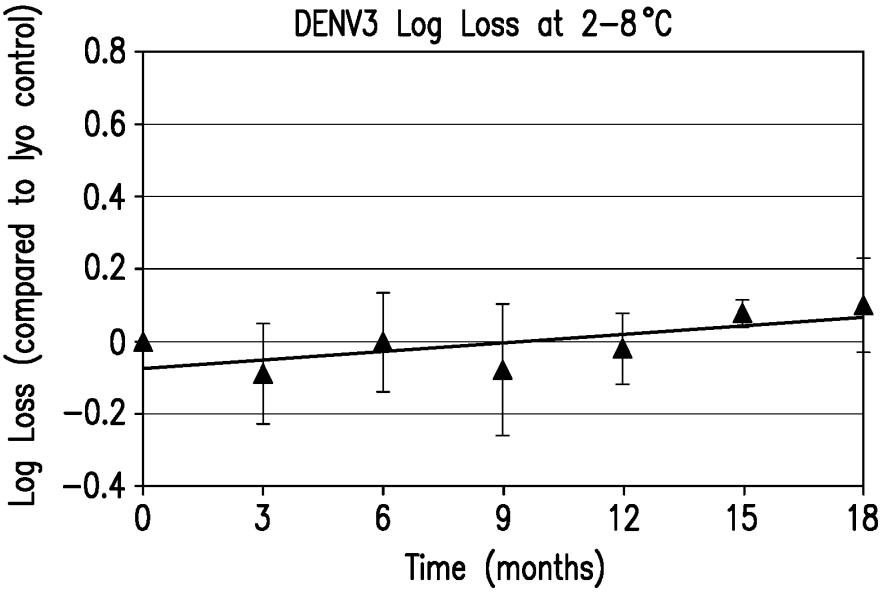


FIG.19C

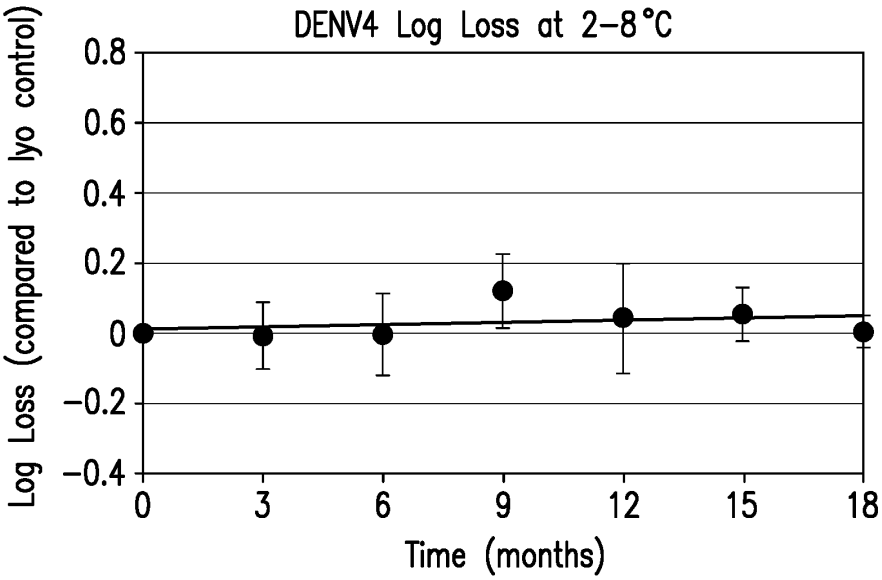


FIG.19D